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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,999	03/16/2001	David M. Neville	14028.0284U2	7991

36339 7590 04/07/2004

NATIONAL INSTITUTE OF HEALTH
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ATLANTA, GA 30303

EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/810,999

Applicant(s)

NEVILLE ET AL.

Examiner

G. R. Ewoldt, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 8, 10, 12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) 3 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 8, 10, 12 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 2, 4, 8, 10, 12, and 13 are being acted upon.
2. Applicant's amendment and remarks, filed 1/14/04, are acknowledged. In view of Applicant's amendment, the previous rejection under the first paragraph of 35 U.S.C. 112 of Claims 1, 2, 4, 8, 10, and 12 have been withdrawn.
3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claim 13 stands rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

a method for the treatment of diabetes comprising the administration of UCHT1-CRM9, an immunosuppressant, and pancreatic islet cells from a donor,

does not reasonably provide enablement for:

a method for the treatment of diabetes comprising the administration of an immunotoxin, an immunosuppressant, and pancreatic islet cells from a donor, for the reasons of record as set forth in the paper mailed 5/20/03.

Applicant arguments, filed 1/14/04, have been fully considered but are not found persuasive. Applicant argues that the amending of Claim 1 overcomes the rejection.

Applicant is advised that Claim 13 does not depend on Claim 1.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 2, 4, 8, 10, 12, and 13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,103,235 (IDS), for the reasons of record as set forth in the paper mailed 5/20/03.

Applicant arguments, filed 1/14/04, have been fully considered but are not found persuasive. Applicant argues that because the instant application claims the benefit of priority of U.S. Provisional Application No. 60/008,104, U.S. Patent No. 6,103,235 is not available as prior art.

Applicant is advised that the claims to priority, as set forth in the amendment filed 8/13/01, are somewhat confusing. One parent application, 08/878,378, appears to be both a continuation and a continuation in part of PCT/US96/05087. Regardless, the benefit of priority is denied because the '378 application (and its child application, 09/368,069) does not teach a method of treating diabetes employing deoxyspergualin. The instant application also claims the benefit of priority of application 09/380,484. This benefit of priority has also been denied because the '484 application does not teach a method of treating diabetes. The filing date of the instant application is thus its filing date of 3/16/01.

7. Claims 1, 2, 4, 8, 10, 12, and 13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/32137 (1996, IDS), in view of Henretta et al. (1994, IDS), for the reasons of record as set forth in the paper mailed 5/20/03.

Applicant arguments, filed 1/14/04, have been fully considered but are not found persuasive. Applicant argues that the instant application claims the benefit of priority of PCT/US96/05087 (WO 96/32137), thus, it cannot be used as prior art. Applicant is advised that, as set forth in the rejection, WO 96/32137 does not teach a method of treating diabetes employing deoxyspergualin. Accordingly, the benefit of priority has been denied.

8. The following are new grounds for rejection necessitated by Applicant's amendment.

9. Claims 117, 123, 125, and 127 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed

invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically, a method employing an "anti-CD3-diphtheria toxin immunotoxin".

Applicant argues that support for the claim can be found in original Claims 1 and 5-7. Applicant is advised that the original claims support a divalent anti-T cell immunotoxin directed at the CD3 epitope further comprising a diphtheria toxin, but not the broader "anti-CD3-diphtheria toxin immunotoxin" of Claim 1.

10. No claim is allowed.

11. Applicant's amendment or action (filing of new applications) necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

13. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications

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is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Additionally, the Technology Center receptionist can be reached at (571) 272-1600.

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3/22/04
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